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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,556	07/10/2001	Romano Deghenghi	87264-200	7188

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EXAMINER

MAYES, LAURIE A

ART UNIT

PAPER NUMBER

1653

10

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/902,556	DEGHENGHI, ROMANO
	Examiner	Art Unit
	Laurie Mayes	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 October 2002.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-9 and 19-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-9 and 19-25 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \*    c) None of:
- Certified copies of the priority documents have been received.
  - Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1)  Notice of References Cited (PTO-892)      4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      5)  Notice of Informal Patent Application (PTO-152)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.      6)  Other: \_\_\_\_\_

## **DETAILED ACTION**

Applicant's election of Group I, claims 1-9 and 19-25 in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Please note: canceled claims 10-18 are "canceled" and not withdrawn.

The STIC Systems Branch corrected the CRF for SEQ ID NO: 2 by aligning the amino acid numbers.

### ***Information Disclosure Statement***

The references AA-AC are in Japanese and no English abstract nor an explanation of their relevance was provided. The references could not be fully assessed, but they have been considered to the extent possible. Also, it is noted that reference AE claims priority back to these three references.

### ***Specification***

Claims 1-9 and 19-25 are objected to as they contain sequences more than four amino acids in length and fail to recite "SEQ ID NO: \_\_\_\_". See 37 CFR 1.821-1.825. Also, none of the sequences in the body of the specification is identified by a SEQ ID NO.

### ***Claim Objections***

Claim 24 is objected to because of the following informalities: the word "intranasally" is misspelled. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 recites the limitation "the peptide of claim 1 wherein the formula is Gly-Ser-Ser(Octanoyl)-Phe-**Leu**-Ser-Pro-Glu-Ala-Lys-Leu-Gln-Pro-Arg". However, claim 1 states that the formula is "Gly-Ser-Ser(Octanoyl)-Phe-A where A is -OH, NH<sub>2</sub>, Leu-Ser-Pro-Glu-B, or -Ala-Lys-Leu-Gln-Pro-Arg-B, where B is -OH or NH<sub>2</sub>". Thus the formula may be Gly-Ser-Ser(Octanoyl)-Phe- Leu-Ser-Pro-Glu-B or Gly-Ser-Ser(Octanoyl)-Phe- Ala-Lys-Leu-Gln-Pro-Arg-B but may not be Gly-Ser-Ser(Octanoyl)-Phe-**Leu**-Ser-Pro-Glu-Ala-Lys-Leu-Gln-Pro-Arg because B is not Ala-Lys-Leu-Gln-Pro-Arg. There is insufficient antecedent basis for this limitation in the claim.

Claims 1-9 and 19-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terminal amino acid contains an -OH group in a peptide/protein. In the claims, the "Phe" in claims 1 and 25 would have a terminal "-COOH" and where "A" is recited is the "-OH" equivalent to "A" or does the carboxy terminus have "-COOH"? The claims recite amino acids attached to A, where A is -OH. It is unclear whether the applicant is claiming an additional -OH group for each sequence. Also, in claim 7 it is unclear whether the applicant intends "formation" or "formulation", as dependent claim 21 recites "formulation". If "formation" was intended, there is no antecedent basis for the "formulation" of claim 21. Claims 2-9 and 19-24 are included in this rejection as they depend from claim 1 and do not clarify the ambiguity.

***Allowable Subject Matter***

Claims 2-9 and 19-24 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 1 and 25 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

***Conclusion***

**Claims 1-9 and 19-25 are free of prior art.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached on Monday through Friday from 7AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 305-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

*L. Mayes*

Laurie Mayes  
Patent Examiner  
Art Unit 1653  
February 7, 2003

*Gabrielle E. Bugaisky*  
**GABRIELLE BUGAISKY**  
**PRIMARY EXAMINER**